

SEP 12 1996

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pg. 1 of 2

510 (k) SUMMARY

I. ADMINISTRATIVE

Submitter: Maxxim Medical, Inc.
104 Industrial Boulevard
Sugar Land, Texas 77478
713-240-2442

Contact Person: Ernest J. Henley

Date of Preparation: July 8, 1996

II. DEVICE NAME

Proprietary Name: Dermaplex Hydrogel Wound Dressing

Common Name: Wound Dressing

Classification Name: Hydrogel wound and burn dressing

III. PREDICATE DEVICE

Curagel Hydrogel Wound Dressing; Kendall Healthcare Products Co.; K950412

IV. DEVICE DESCRIPTION

The Dermaplex Hydrogel Wound Dressing is a solid hydrogel dressing covered with a polyester liner which is removed prior to application. The product is available in three sizes (3" x 3", 5" x 5", and 6" x 10") and is supplied sterile in sealed aluminum/plastic laminate pouches.

Biocompatibility of the device has been established by a primary dermal irritation test in rabbits and a sensitization test in guinea pigs. The product meets the requirements of the USP Cytotoxicity Test (Agarose Diffusion).

V. INTENDED USE

For the local management of pressure ulcers, stasis ulcers, 1st and 2nd degree burns, and full and partial thickness wounds.

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VI. COMPARISON TO PREDICATE DEVICE

The Dermaplex Hydrogel Wound Dressing is similar in composition, function and intended use to the Curagel Hydrogel Wound Dressing (Kendall Healthcare Products Co.) and other legally marketed wound dressing products consisting of solid hydrogel.

Accordingly, Maxxim Medical, Inc. concluded that the Dermaplex Hydrogel Wound Dressing is as safe and effective for its intended use and performs at least as well as legally marketed predicate devices, such as the Curagel Hydrogel Wound Dressing.